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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,380	01/27/1999	MATITYAHU FRIDKIN	FRIDKIN=1	3626

7590 07/29/2003

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WASHINGTON, DC 20001

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/29/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/117,380

Applicant(s)

FRIDKIN ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 12, 13 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2-9, 12, 13 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/5/2003 has been entered.

Applicants previous amendment of claim 25, Paper No. 30, 4/4/2003 and applicants current amendment of claim 25, Paper No. 32, 5/5/2003, have been entered and are acknowledged.

Claims 2-9, 12, 13 and 25 are still at issue and are present for examination.

Applicants' arguments filed on 4/4/2003, Paper No. 30, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-9, 12, 13 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A similar rejection to based on applicants previous amendment of claim 25 was stated in the previous office action. Applicants have again amended claim 25, and traverse the rejection as it applies to the currently amended claims.

Applicants newly amended claim 25 (claims 2, 3, 4, 5, 6, 7, 8, 9, 12 and 13 dependent from) is rejected as containing new matter because the recitation "...with the proviso that the residue at 89 is not Leu, the proviso that the residue at 90 is not Glu, the proviso that the residue at 91 is not Ala, the proviso that the residue at 92 is not Ile, the proviso that the residue at 94 is not Ala or Val, the proviso that the residue at 95 is not Ser, the proviso that the residue at 96 is not Ile all at the same time;...", is not supported by the original disclosure.

Applicant continues to traverse this rejection (Paper No. 30, 4/9/2003) and submit a number of exhibit claims A-G as a means of explaining and supporting applicants position. Applicant presents Claim A, which is the same as claim 25, except that the proviso reads "with the proviso that the residue at 89 is not Leu". Applicants submit that surely the examiner would concede that this claim meets the description requirement on the basis that "If a genus is disclosed in the specification, including a number of specific species, then that genus excluding one of the specified species also satisfies the written description requirement."

This argument as it applies to Claim A and each of the additional exhibit claims B-G is not found persuasive. To this line of reasoning applicant is reminded that applicants original claim and disclosure was directed to a genus of molecules comprising a great number of species. While applicants disclose the genus, applicants do not disclose the great majority of the encompassed species. If applicants were to propose an amendment to the claims to a specific species encompassed within the disclosed genus, a species of which there was not prior support in the disclosure for, a rejection would be made stating that while applicants had support for the claimed genus, applicants disclosure did not support the newly proposed species. Analogously applicants do not have support in the original disclosure for the originally supported genus minus a specific species of which there is no support for. In effect applicants do not have support for this newly proposed genus.

Applicants cite the case *In re Johnson*, 194 USPQ 187, 196 (1977) to support their position as well as the MPEP 2173.05 (i). Each of the references are acknowledged however, applicants argument is still not found persuasive.

In *In re Johnson*, 194 USPQ 187, 196 (1977), "Fifty specific choices are mentioned for the E precursor compound, a broad class is identified as embracing suitable choices for the E' precursor compound, and twenty-six "examples" are disclosed which detail fifteen species of polyarylene polyethers. Only fourteen of those species and twenty-three of the "examples" are within the scope of the claims now on appeal. Two of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is claiming less than the full scope of his

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disclosure. Herein lies the distinction between *In re Johnson*, 194 USPQ 187, 196 (1977) and the current application, While in the Johnson case applicants were deleting two of the many choices which were disclosed, in the present case applicants are attempting to delete a choice which was not originally disclosed.

Applicants assert that the hydrophobic residue at position 89 may be Leu is disclosed in the present specification and thus if the entire genus is disclosed, specifically including the species in which the residue at position 89 is Leu, then the entire genus is also disclosed minus the species in which the residue corresponding to position 89 is Leu. Applicants submit that such a claim as exhibit A is not anticipated by Barr and is supported by written description of the present specification. Applicants make similar arguments and assertions regarding claim exhibits B-G. Applicants assertion that these claim exhibits are not anticipated by Barr et al. is persuasive, however applicants assertion that these claim exhibits are supported by the original specification is not found persuasive, much less is applicants "cumulative effect " claim (i.e. claim 25) of the combination of these exhibit claims considered to be supported by the original specification for the reasons discussed above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 9 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Insley et al. (European Patent Application 0 155 188).

Insley et al. teach a substantially pure protein comprising a mutant amino acid sequence of mammalian alpha-1-antitrypsin wherein the methionine at amino acid position 358 is mutated to phenylalanine and pharmaceutical compositions comprising said protein, for use in the treatment of conditions such as emphysema and other lung disorders. The disclosed mutant alpha-1-antitrypsins are capable of inhibiting elastase and trypsin activity. The above disclosed mutant alpha-1-antitrypsin comprises the amino acid sequence "...leu₃₅₃-glu-ala-ile-pro-**phe**-ser-ile₃₆₀..." which anticipates claims 25, 2 and 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Insley et al. (European Patent Application 0 155 188).

As discussed above, Insley et al. teach a substantially pure protein comprising a mutant amino acid sequence of mammalian alpha-1-antitrypsin wherein the methionine at amino acid position 358 is mutated to phenylalanine and pharmaceutical

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compositions comprising said protein for use in the treatment of conditions such as emphysema and other lung disorders. The disclosed mutant alpha-1-antitrypsins are capable of inhibiting elastase and trypsin activity. The above disclosed mutant alpha-1-antitrypsin comprises the amino acid sequence "...leu₃₅₃-glu-ala-ile-pro-**phe**-ser-ile₃₆₀...".

One of ordinary skill in the art would be motivated to use the pharmaceutical compositions comprising a variant of mammalian alpha-1-antitrypsin wherein the variant comprises the sequence "...leu₃₅₃-glu-ala-ile-pro-**phe**-ser-ile₃₆₀..." as taught by Insley et al. for treatment of conditions such as emphysema and other lung disorders related to progressive digestion of lung sacs in which the patient has an inadequate level of alpha-1-antitrypsin. The reasonable expectation of success comes from the results and teachings of Insley et al. and the high degree of knowledge in the art.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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July 25, 2003